

NARRATIVE STATEMENT

On July 28, 1997, Medtronic, Inc., a world leader in the development of medical implant devices, filed a petition urging the Commission to issue a notice of proposed rule making calling for the creation of the Medical Implant Communications Service ("MICS") in the 402-405 MHz band under Part 95 of the Rules. See Petition for Rule Making filed by Medtronic, Inc., RM No. 9157. A copy of that petition is attached for the staff's convenience.

MICS operations would provide for the transmission of data to and from implanted medical devices such as cardiac pacemakers and defibrillators via high speed (100 kbps or more) short-range ultra lower power (25 microwatts) wireless links. MICS systems would replace the cumbersome, slow-speed inductive coupling technology now used. By this application, Medtronic is requesting an experimental radio license to develop and test MICS systems.

MICS requires a power of only -16 dBm (25 uW) EIRP to be effective and will be used largely indoors usually in urban areas, which virtually eliminates the potential for MICS to interfere with other services.

The experimentation will use digital FM modulated signals with bandwidth which would not extend beyond the specific frequencies requested. The 300 kHz necessary bandwidth is the maximum that is needed given the maximum data rate and modulation scheme, which assumes 1 bit/Hz and 50 kHz peak frequency deviation. As shown in Appendix C of the attached Petition for Rule Making, operation at the requested power level is not expected to cause interference to existing licensees.

The equipment to be tested will come from multiple manufacturers. The experimentation would involve a maximum of 10 programming units (base stations) and 100 implants (mobiles).

Medtronic understands that the FCC permits (1) companies to enter into agreements and contracts to manufacturer new products; (2) manufacturers to sell, but not deliver, products on a

conditional basis to wholesalers and retailers; (3) entities to operate prototype devices for, among other things, compliance testing, demonstration at trade shows and other exhibitions with appropriate notices displayed; and (4) companies to evaluate product performance and customer acceptability at the manufacturer's facilities or at certain non-residential sites during the developmental, design, and pre-production stages. See Marketing Rule Revisions, § 2.803; Part 15 Revisions, 6 FCC Rcd 1683, 1685 (1991).

Notwithstanding these general rules, however, the FCC requires entities to seek experimental or other authorization (1) to operate devices in frequency bands that normally are licensed and (2) to use products in residential environments. Such authority may be granted under the FCC's experimental rules set forth in Part 5 of the Code of Federal Regulations, 47 C.F.R. Part 5 (1996).

Accordingly, Medtronic seeks an experimental license to conduct studies in licensed bands and in residential environments as permitted under Section 5.202(j) of the Commission's rules. 47 C.F.R. § 5.202(j) (1996). Those rules permit companies to conduct such studies, as well as to distribute, provided that: (1) participants are advised that the service or device is granted under experimental authority and is strictly temporary; and (2) the devices are owned by the licensee. Grant of such authority would allow Medtronic to study products under experimentation.

As a final matter, please note that the experimentation proposed in this application employs ultra low power and thus is categorically excluded from the FCC's requirements associated with human exposure to RF radiation. Thus, the proposed operation would not have a significant environmental effect under Section 1.1307 of the FCC's rules.

Although no human implantation will be conducted under the requested authorization, the grant of this application will allow Medtronic to develop an innovation that would greatly improve the utility of implanted medical devices and enhance the quality of life of patients. Accordingly, Medtronic submits that a grant will serve the public interest, convenience, and necessity.